510(k) Summary
for the Sorin Group Deutschland GmbH
Stöckert Air Purge Control (APC) System

JAN 18 2011

(per 21 CFR 807.92 and *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm*)

1. SPONSOR/APPLICANT

Sorin Group Deutschland GmbH
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80939 Munich
Germany
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Contact: Renate Goebert

Date prepared: January 13, 2010

2. DEVICE NAME

Proprietary Name:	Stöckert Air Purge Control (APC) System
Common/Usual Name:	Cardiopulmonary bypass bubble detector and sensor
Classification Name:	Cardiopulmonary bypass bubble detector (21 CFR 870.4205; Product Code: KRL)

3. PREDICATE DEVICES

- Stöckert Air Purge Control (APC) System for S5 System Model 23-45-05 (K091007)
- Stöckert Air Purge Control (APC) System (K041558)

4. DEVICE DESCRIPTION

- **Physical description**
  The Stöckert APC System consists of the APC sensor module (Catalog Number: 23-45-22), 3-joint mast holder with fast clamp connectors for two bubble sensors, 420mm (Catalog Number: 23-26-96), bubble sensor for 3/8 inch tubing (Catalog Number: 23-07-50), and ultrasonic gel, bottle, 250 mL (Catalog Number: 96-06-10). All of these components are identical to those used with the Stöckert S5 System (K091008).

- **How the device functions**
  The Stöckert APC can be operated automatically and manually using the APC displet of the heart lung machine.

- **Scientific concepts that form the basis for the device**
  The Stöckert APC bubble trap is placed just before the venous bubble trap of the Synergy™/ECC.O™. When bubble activity is sensed, the assigned roller pump on the heart lung machine console begins operation to remove a set tubing volume (as determined by tubing size and pump speed (RPM)) or to run for a set time (in seconds) at a perfusionist-selected flow rate. This fluid is pumped into an appropriate blood collection reservoir. The technology of the Stöckert APC is based on the technology of the Stöckert Air Purge Control System (K041558).

- **Significant physical and performance characteristics of the device, such as device design, material used, and physical properties**
  The Stöckert APC is used for detecting air in the venous line and removing air from the venous bubble trap of the Synergy™/ECC.O™ System tubing circuit. Specifications are provided in the SCP Plus System/APC Operating Instructions.

5. INTENDED USE/INDICATION FOR USE

The Stöckert Air Purge Control (APC) System detects air in the venous line and removes air from the venous bubble trap of the Synergy™/ECC.O™ System tubing circuit. The Synergy™/ECC.O™ shall only be used in conjunction with the Stöckert S5 (or any compatible system using the S5 firmware versions of 3.0 or greater) and the SCP Plus System. The Stöckert S5 System is indicated for speed controlled pumping of blood through the cardiopulmonary bypass circuit for durations of six hours or less, left ventricular venting, cardiotomy suction and administration of cardioplegia solution.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The technological characteristics of the Stöckert APC System described in this Traditional 510(k) Premarket Notification are identical to that reviewed by the FDA in K091007. They use the same hardware, firmware, and electronics as well as components including the APC sensor module, the bubble sensors, and the 3-joint mast holder. Both Systems are used for detecting air in the venous line and removing it from the venous bubble trap of the Synergy/ECC.O System. The APC used with both heart lung machines is controlled via touchscreen and its performance is unchanged when integrated with the heart lung machine.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No comparative non-clinical testing served as the basis for substantial equivalence.

The Stöckert Air Purge Control (APC) System was tested in conjunction with the heart lung machine for safety in accordance with IEC60601-1 (with National Deviations), for electromagnetic compatibility in accordance with IEC60601-1-2, and performance according to a formal prospectively defined functional acceptance test and simulated use/in-use validation testing. Testing of the Stöckert Air Purge Control (APC) System (hardware, firmware, and performance) has demonstrated that the System fulfills prospectively defined performance criteria and that the System meets user needs.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Formal clinical testing of the Stöckert Air Purge Control (APC) System has not been performed. Therefore, this section does not apply.

9. SUMMARY OF OTHER INFORMATION

No information other than that described was provided.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the non-clinical testing provided in this premarket notification, the Stöckert Air Purge Control (APC) System integrated with the Stöckert S5 performs in an identical manner as the System integrated with the Sorin C5 System, thus demonstrating that there are no differences and that the devices are substantially equivalent and perform in accordance with specifications and meets user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sorin Group Deutschland GmbH
c/o Ms. Rosina Robinson
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

JAN 18 2011

Re: K103469
Trade/Device Name: Stöckert Air Purge Control (APC) System
Regulation Number: 21 CFR 870.4205
Regulation Name: Cardiopulmonary bypass bubble detector
Regulatory Class: II
Product Code: KRL
Dated: November 24, 2010
Received: November 24, 2010

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

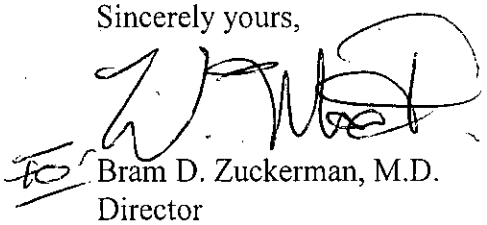
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103469

Device Name: Stöckert Air Purge Control System

Indications for Use:

The Stöckert Air Purge Control (APC) System detects air in the venous line and removes air from the venous bubble trap of the Synergy™/ECC.O™ System tubing circuit. The Synergy™/ECC.O™ shall only be used in conjunction with the Stöckert S5 (or any compatible system using the S5 firmware versions of 3.0 or greater) and the SCP Plus System.

The Stöckert S5 System is indicated for speed controlled pumping of blood through the cardiopulmonary bypass circuit for durations of six hours or less, left ventricular venting, cardiotomy suction and administration of cardioplegia solution

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103469